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Pfizer and BioNTech to Potentially Supply the EU with 200 Million Doses of mRNA-based Vaccine Candidate Against SARS-CoV-2

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- *The proposed agreement is intended to provide a supply of 200 million doses and an option to purchase additional 100 million doses, with deliveries starting by the end of 2020, subject to regulatory approval*
- *The vaccine supply for the EU would be produced by BioNTech's manufacturing sites in Germany and Pfizer's manufacturing site in Belgium*
- *Pfizer and BioNTech are on track to seek regulatory review of BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021*

NEW YORK & MAINZ, Germany--(BUSINESS WIRE)-- Pfizer (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced that they had concluded exploratory talks with the European Commission for a proposed supply of 200 million doses of their investigational BNT162 mRNA-based vaccine candidate against SARS-CoV-2 to European Union (EU) Member States, with an option for further 100 million doses. Deliveries would be starting by the end of 2020, subject to clinical success and regulatory authorization. The companies will now enter into contract negotiations with the European Commission.

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The proposed supply agreement with the European Commission would represent the largest initial order of vaccine doses for Pfizer and BioNTech to date. Vaccine doses for Europe would be produced in BioNTech's German manufacturing sites, as well as in Pfizer's manufacturing site in Belgium. If regulatory approval for the BNT162b2 vaccine candidate is received, the European Commission would lead the process for allocation of the vaccine doses among the 27 EU Member States.

"Pfizer and BioNTech's anticipated agreement with the European Commission is an important step forward in our shared goal to have millions of doses of a vaccine against COVID-19 available for vulnerable populations before the end of the year. We would like to thank the European Commission for its commitment and confidence in our development efforts," said **Albert Bourla, Chairman and CEO, Pfizer**. "We have activated our supply chain, most importantly our site in Belgium, and are starting to manufacture so that our vaccine would be available as soon as possible, if our clinical trials prove successful and regulatory approval is granted."

"As a company founded in the heart of Europe, we are pleased to have concluded exploratory discussions with the European Commission, which would be our largest initial order to date. Our aim is to develop a safe and effective vaccine to contribute to bringing this pandemic to an end in Europe and across the world. Today's

decision is a further illustration of how collaboration and solidarity can help address a global health crisis as an international community," said **Ugur Sahin, M.D., CEO and Co-founder of BioNTech.**

In addition to engagements with governments, Pfizer and BioNTech have provided an expression of interest for possible supply to the COVAX Facility, a mechanism established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations (CEPI) and World Health Organization (WHO) that, using a range of technology platforms, aims to provide governments, including those in the emerging markets, with early access to a large portfolio of COVID-19 candidate vaccines produced by multiple manufacturers across the world.

About the BNT162 Vaccine Candidate Program

The BNT162 program is based on BioNTech's proprietary mRNA technology and supported by Pfizer's global vaccine development and manufacturing capabilities. Two of the companies' four investigational vaccine candidates – BNT162b1 and BNT162b2 – received Fast Track designation from the U.S. Food and Drug Administration (FDA), based on preliminary data from Phase 1/2 studies that are currently ongoing in the U.S. and Germany as well as animal immunogenicity studies. During preclinical and clinical studies, BNT162b1 and BNT162b2 emerged as strong candidates based on assessments of safety and immune response.

On July 27, Pfizer and BioNTech announced that following extensive review of preclinical and clinical data from Phase 1/2 clinical trials, and in consultation with the FDA's Center for Biologics Evaluation and Research (CBER) and other global regulators, the companies selected the BNT162b2 vaccine candidate to move forward into a Phase 2/3 study. BNT162b2 encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S), which is the target of virus neutralizing antibodies.

About the Phase 2/3 Study

In the late-stage trial, Pfizer and BioNTech are studying a 30µg dose level in a 2-dose regimen among up to 30,000 participants aged 18 to 85 years. The companies have selected approximately 120 sites globally, including those in regions with significant expected SARS-CoV-2 transmission, and are working to reach a diverse population and enroll those volunteers at increased risk for the infection with the virus. The Phase 2/3 trial enrollment to date has exceeded 25,000 participants with a second dose underway. Assuming clinical success, Pfizer and BioNTech are on track to seek regulatory review for BNT162b2 as early as October 2020 and, if regulatory authorization or approval is obtained, currently plan to supply up to 100 million doses worldwide by the end of 2020 and approximately 1.3 billion doses by the end of 2021. To meet those anticipated quantities and milestones, the companies have produced sufficient supply for their 30,000 participant Phase 2/3 clinical trial and have begun to produce and stockpile their pandemic supply.

The BNT162 vaccine candidate is not currently approved for distribution anywhere in the world. Both collaborators are committed to developing these novel vaccines with preclinical and clinical data at the forefront of all their decision making.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than

170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of September 7, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine, a potential agreement with the European Commission to supply BNT162 and other potential agreements, the BNT162 mRNA vaccine program, and modRNA candidates BNT162b2 and BNT162b1 (including qualitative assessments of available data, potential benefits, expectations for clinical trials and timing of regulatory submissions, anticipated manufacturing, supply and distribution), that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preliminary data, including the possibility of unfavorable new preclinical or clinical trial data and further analyses of existing preclinical or clinical trial data that may be inconsistent with the data used for selection of the BNT162b2 vaccine candidate and dose level for the Phase 2/3 study; the risk that clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications; whether regulatory authorities will be satisfied with the design of and results from these and future preclinical and clinical studies; whether and when any biologics license and/or emergency use authorization applications may be filed in any jurisdictions for BNT162b2 or any other potential vaccine candidates; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine candidate's benefits outweigh its known risks and determination of the vaccine candidate's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; manufacturing capabilities or capacity, including whether the estimated numbers of doses can be manufactured within the projected time periods indicated; whether and when a definitive supply agreement with the European Commission will be reached; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.Pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer.

For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the timing to initiate clinical trials of BNT162 and anticipated publication of data from these clinical trials; the timing for any potential emergency use authorizations or approvals; our expectation to agree to final terms with and enter into a definitive agreement with the European Commission; the potential to enter into additional supply agreements with other jurisdictions or the COVAX Facility; the potential safety and efficacy of BNT162; the collaboration between BioNTech and Pfizer to develop a potential COVID-19 vaccine; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and, if approved, market demand, including our production estimates for 2020 and 2021. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: competition to create a vaccine for COVID-19; the ability to produce comparable clinical results in larger and more diverse clinical trials; the ability to effectively scale our productions capabilities; and other potential difficulties. For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F filed with the SEC on March 31, 2020, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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